

VU Research Portal

The smallest worthwhile effect of primary care physiotherapy did not differ across musculoskeletal pain sites

Christiansen, David H.; de Vos Andersen, Nils Bo; Poulsen, Per H.; Ostelo, Raymond W.

published in

Journal of Clinical Epidemiology
2018

DOI (link to publisher)

[10.1016/j.jclinepi.2018.05.019](https://doi.org/10.1016/j.jclinepi.2018.05.019)

document version

Publisher's PDF, also known as Version of record

document license

Article 25fa Dutch Copyright Act

[Link to publication in VU Research Portal](#)

citation for published version (APA)

Christiansen, D. H., de Vos Andersen, N. B., Poulsen, P. H., & Ostelo, R. W. (2018). The smallest worthwhile effect of primary care physiotherapy did not differ across musculoskeletal pain sites. *Journal of Clinical Epidemiology*, 101, 44-52. <https://doi.org/10.1016/j.jclinepi.2018.05.019>

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal ?

Take down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

E-mail address:

vuresearchportal.ub@vu.nl

ORIGINAL ARTICLE

The smallest worthwhile effect of primary care physiotherapy did not differ across musculoskeletal pain sites

David H. Christiansen^{a,b,*}, Nils-Bo de Vos Andersen^c, Per H. Poulsen^a, Raymond W. Ostelo^{d,e}

^aDepartment of Occupational Medicine, Regional Hospital West Jutland—University Research Clinic, Gl. Landevej 61, 7400 Herning, Denmark

^bDepartment of Clinical Medicine, Health, Aarhus University, Palle Juul-Jensens Boulevard 82, 8200 Aarhus, Denmark

^cPrimary Health Care and Quality Improvement, Central Denmark Region, Skottenborg 26, 8800 Viborg, Denmark

^dDepartment of Health Sciences, VU University, de Boelelaan 1081 HV, Amsterdam, The Netherlands

^eDepartment of Epidemiology and Biostatistics and the Amsterdam Movement Sciences Research Institute, VU University Medical Centre, de Boelelaan 1081 HV, Amsterdam, The Netherlands

Accepted 19 May 2018; Published online 29 May 2018

Abstract

Objectives: To determine and compare estimates of the smallest worthwhile effect (SWE) for physiotherapy in neck, shoulder, and low-back pain patients and to investigate the influence of sociodemographic, clinical, and psychological factors on these estimates.

Methods: A structured telephone interview was conducted before treatment was commenced in 160 patients referred for primary care physiotherapy. The benefit-harm trade-off method was used to estimate the SWE of physiotherapy for the following outcomes; pain, disability, and time to recovery, compared with the improvement achieved without any treatment (natural course). Regression analyses were used to assess the influence of sociodemographics, clinical variables, and intake scores on pain, disability, and psychological scales.

Results: The median SWE for improvements on pain and disability was 20% (interquartile range 10%–30%), and the SWE for time to recovery was 10 days (interquartile range 7–14 days) over a period of 6 weeks. These estimates did not differ with respect to pain location (neck, shoulder, or back) and were generally unaffected by sociodemographic, clinical, and psychological factors.

Conclusion: People with neck, shoulder, and low-back pain need to see at least 20% of additional improvement on pain and disability compared with natural recovery to consider that the effect of physiotherapy is worthwhile, given its costs, potential side effects, and inconveniences. © 2018 Elsevier Inc. All rights reserved.

Keywords: Smallest worthwhile effect; Minimal important change; Patient-reported outcome measures; Musculoskeletal disorders; Physiotherapy

1. Introduction

Pain or discomfort of the neck, shoulder, and lower back can adversely affect daily living and entail substantial health care resource expenditure, work absenteeism, and disability [1]. In Denmark, approximately 14% of all adult consultations with general practitioners are due to musculoskeletal disorders [2]. In primary care, physiotherapy practice patients with neck, shoulder, and low-back pain account for 21%, 12%, and 26% of patients seeking treatment, respectively [3]. Results from clinical trials support the use of physiotherapy (manual therapy and exercise) for these patient groups [4], but methods to determine whether the observed treatment effects are of clinical importance is an ongoing topic of discussion.

Numerous studies have been conducted to obtain empirical evidence for clinically important effect estimates within the musculoskeletal field, but most have made use of anchor or distribution-based methods [5–7]. In anchor-based methods, clinically important effects are estimated by comparing changes in scores on health-related outcome measures (e.g., disability) to a threshold set by an external anchor, that is, a global rating of change scale. In distribution-based methods, change above random variation on a health-related outcome measure or effect sizes exceeding a certain magnitude (e.g., > 0.5) is considered of clinical importance [8,9].

Recently, the use of anchor and distribution-based methods has been criticized, as they do not incorporate patients' perceptions of the magnitude of effect or provide estimates specific to the intervention at hand [6]. The authors of a recent systematic review [6] argue that decisions about what constitutes a worthwhile effect should instead be based on the benefit-harm trade-off approach. This method takes into account contextual factors such as the costs,

Conflict of interest: None.

* Corresponding author. Tel.: +45-21688431; fax: +45 7843 3518.

E-mail address: David.Christiansen@vest.rm.dk (D.H. Christiansen).

What is new?**Key findings**

- To consider that the effect of physiotherapy is worthwhile, taking into account its costs, potential side effects, and inconveniences, people with neck, shoulder, and low-back pain need to experience at least 20% additional improvement on pain and disability and to speed up their recovery by 10 days over natural recovery, that is, improvement without treatment, over a period of 6 weeks.
- These perceptions do not seem to differ with pain location and also seem largely unaffected by socio-demographic, clinical, and psychological factors.

What this adds to what was known?

- This study determines and compares estimates of the SWE for primary care physiotherapy in patients with musculoskeletal disorders of the neck, shoulder, and lower back.

What is the implication and what should change now?

- Findings from this study may serve to guide clinicians, researchers, and policy makers when evaluating the effectiveness of physiotherapy interventions for musculoskeletal disorders in primary health care settings.
- The findings may also inform sample size calculations when designing randomized clinical trials as the best available estimate for a clinically relevant difference should be used to calculate sample size.

2 weeks for patients to perceive that the effect of physiotherapy is worthwhile. The study also demonstrated that the SWE estimates of a treatment course based on nonsteroid anti-inflammatory drugs was significantly larger than the SWE estimates for physiotherapy.

These findings indicate that SWE should not be evaluated without a comparator condition (no treatment) and that SWE should include references to the costs, risks and inconveniences of the specific intervention, as among patients who seek treatment for low-back pain, different estimates would be elicited for different therapies. Furthermore, these estimates may vary across patient populations and be affected by differences in health care systems between countries [16]. Further factors such as symptom severity, past experience with physiotherapy, and out-of-pocket expenses in relation to treatment could also influence this perception. In Denmark, physiotherapy services in primary care are partially covered by public health insurance through the Danish Health Care Reimbursement Scheme [17]. However, it is not unusual for people to take out additional private health insurance to supplement their standard entitlement from the Danish public health insurance scheme to gain partial or full coverage of any costs. According to the results of a previous Danish cohort study, 30% of patients who are referred for physiotherapy due to musculoskeletal pain have taken out supplemental insurance [3].

Thus, the aim of the present study was to propose estimates of the SWE for physiotherapy for neck, shoulder, and low-back pain using the benefit-harm trade-off method. The specific objectives were (1) to determine the distribution of the SWE for physiotherapy when compared with the improvement achieved without any treatment (natural course) and to compare these estimates by primary pain complaint (neck, shoulder, or back) and (2) to investigate if sociodemographic, clinical, and psychological factors influence these estimates.

risks, and inconveniences that are associated with a specific intervention [10]. In that manner, the smallest worthwhile effect (SWE) can be conceived in terms of hypothetical differences in outcome with or without intervention rather than in terms of the changes in outcome that occur over the course of a treatment, which may be influenced by natural recovery, regression to the mean, and placebo effects [6].

The benefit-harm trade-off method has previously been used to determine the SWE of interventions for the common cold [10], chronic obstructive pulmonary disease [11], and for cancer therapies [12–14], but its use within the musculoskeletal field is sparse. The benefit-harm trade-off method was only recently used to estimate the SWE of interventions for chronic low-back pain [15]. The authors of the abovementioned study found that, when compared to no treatment, patients seeking physiotherapy for chronic low-back pain, the treatment must reduce pain and disability by at least 15% or 15 points on a 100-point scale and speed up recovery by 2 days over a period of

2. Material and methods

2.1. Study population and design

The study was nested in a larger prospective cohort study evaluating the utility of standardized electronic data collection tools for patients seeking treatment for neck, shoulder, or low-back pain in 23 physiotherapy practices across Denmark from January to June 2016 [18]. Permission to contact the patient by telephone was obtained by secretarial staff. Consent for the telephone interview was obtained by the interviewer, and a structured interview was conducted before treatment was commenced. Furthermore, a web-based questionnaire was completed by the patients before their first consultation. The inclusion criteria were age 18 years or above, sufficient Danish skills to participate in the interview, and complete the questionnaire independently. No specific diagnostic criteria was applied other than neck, shoulder, or low-back pain presented at referral.

2.2. Estimation of the SWE

For each patient, a structured interview was conducted to estimate the SWE of a course of physiotherapy treatment for neck, shoulder, or low-back pain. Interviews were performed by a trained interviewer (D.H.C.) and based on a previously developed standardized script [6,15]. These original scripts were translated and adapted to Danish health care. The translated script was reviewed by three experienced clinical physiotherapists to ensure that it matched current physiotherapy practice in Denmark. The script was then pilot-tested through telephone interviews with 20 patients and adjusted accordingly. The English and Danish language versions of the script are available in [Appendix A](#).

The procedure for the interview was as follows: initially the purpose of the study was explained to the patient and data on the patient's past experience with physiotherapy were collected. Next, the interviewer in lay and general terms explained how physiotherapy is usually administered, including costs and potential side effects (e.g., soreness) (see [Appendix A](#)). Thereafter, the interviewer explained to the patient what is known about the natural course of neck, shoulder, and back pain and how much improvement may occur owing to natural recovery (improvement without any treatment). More specifically, the interviewer informed

the patient that, without physiotherapy, he or she could expect a 30% improvement in pain, disability, and recovery from the current episode within 6 weeks. This represented the counterfactual factor with which the effect of physiotherapy was compared. The time interval and magnitude of the natural course was based on knowledge from previous studies of individuals with neck and back pain [19,20]. Next, the patient was asked how much additional improvement (improvement additional to natural recovery) in symptom severity he or she would expect to see if receiving physiotherapy. The magnitude of this hypothetical effect was then gradually reduced. At each iteration, the patient was asked to judge whether he or she still would consider this effect large enough—that is, worthwhile—when taking into account the costs, the possible side effects, and the inconveniences of physiotherapy. This procedure was repeated for each of the three outcomes of interest (i.e., improvement in pain, disability, and reduction in the number of days to recovery). The smallest expected effect by which the patient would still choose physiotherapy (patient still answered yes) represented the SWE estimate for the patient. Improvements in pain and disability were expressed as 10% symptom reduction increments, and time to recovery was measured in days.

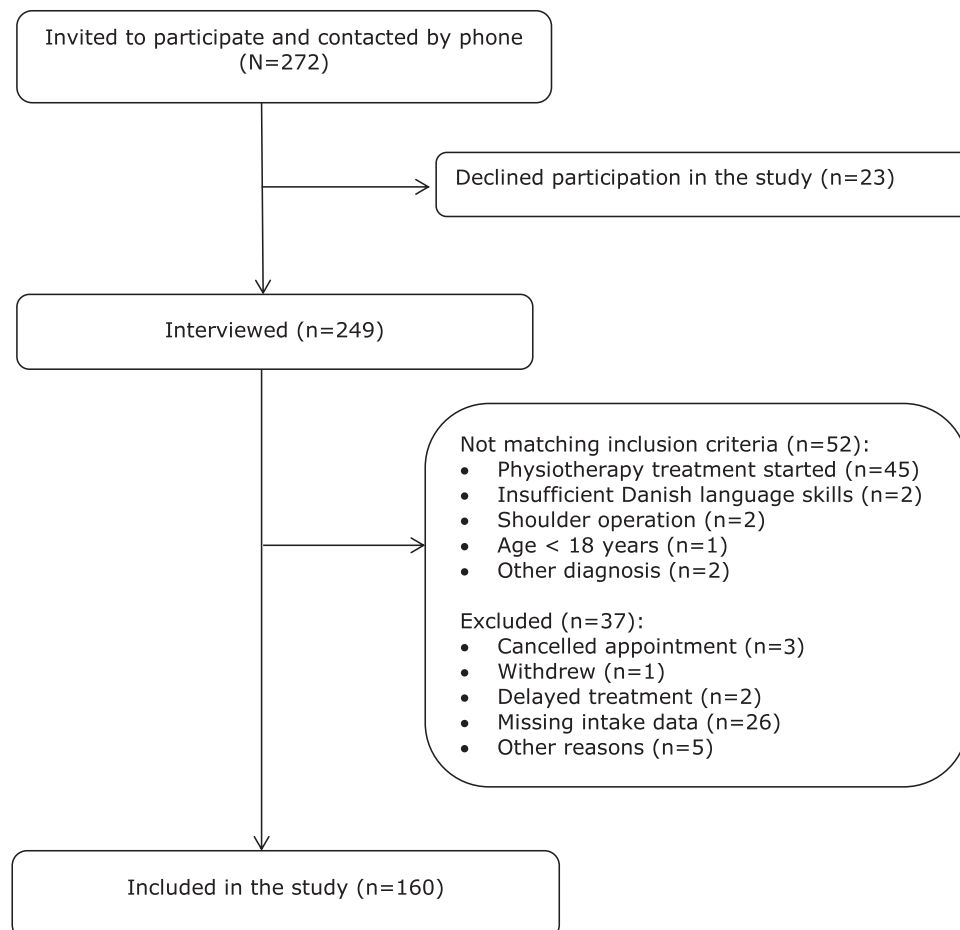


Fig. 1. Study flow chart.

Table 1. Patient characteristics

Variables	(n = 160)
Pain site	
Lower back	66 (41.3)
Shoulder	53 (33.1)
Neck	41 (25.6)
Gender	
Woman	90 (56.3)
Men	70 (43.8)
Age	
Years mean, (SD)	50.8 (14.2)
Work status	
Working	90 (56.3)
Sick leave/subsidised job	18 (11.3)
Unemployed/leave/training	15 (9.4)
Retired	37 (23.1)
Previous experience with physiotherapy	
No	31 (19.4)
Yes	129 (80.6)
Private health insurance	
No	111 (69.4)
Yes	49 (30.6)
Duration of symptoms	
<3 months	82 (51.3)
≥3 months	78 (48.8)
Taking pain medication (daily)	
No	63 (39.4)
Yes	97 (60.6)
Intake scores	
Pain 0–10, mean, (SD)	6.3 (1.9)
Disability level 0–100 ^a , mean (SD)	55.5 (26.5)
Fear avoidance 0–20, mean (SD)	11.2 (5.1)
Psychological well-being 0–100, mean (SD)	56.7 (19.8)

Abbreviation: SD, standard deviation.

Values are numbers (percentages) unless otherwise stated.

^a Standardized score of disability.

2.3. Questionnaire and clinical assessment

The web-based questionnaire included questions on work status, duration of pain, and use of medication [3,21]. The domains of pain, disability, pain behavior, and psychological

well-being were measured using validated scales; the Numeric Pain Rating Scale [22], the Neck Disability Index (NDI) [7,23], the Disabilities of the Arm, Shoulder and Hand (Quick DASH) [24,25], the Roland Morris Questionnaire (RMQ) [26,27], the Musculoskeletal Pain Screening Questionnaire [28–30], and the WHO 5 Well-being Index [31,32]. Furthermore, we included data from standardized registration forms on referral and clinical assessment, such as time of referral, primary pain complaint, and private health insurance. All data were collected and administered via an existing Danish online Physiotherapy Database (www.fysdb.dk).

2.4. Statistical analysis

Sample size estimation was based on the general recommendations of a minimum of 50 subjects for a method-comparison study [33]. Thus, we aimed to include 50 patients for SWE estimation of each pain location (i.e., neck, shoulder, and back) and a minimum of 150 patients in total to insure at least 10 subjects per indicator variable in multivariable regression analyses [34].

The distribution of the estimates of the SWE for each outcome was calculated. Differences between groups with respect to pain location (neck, shoulder, or back) were quantified and analyzed using simple interval-censored linear regression (improvement in pain and disability) and linear regression (days to recovery). Interval-censored linear regression takes into account that, when using 10-unit intervals for improvement as we did, the actual “true” value is somewhere in that interval [35]. Multivariable regression analyses were used to assess any possible influence of sex, age, work status, duration of symptoms, private health insurance, past experience with physiotherapy, daily pain medication, and intake scores on pain, disability, pain-related fear, and psychological well-being on SWE for each outcome. All models were adjusted for possible clinic-related cluster effect and calculated with robust standard errors [33]. The precision of the estimates was expressed by 95% confidence intervals (CIs). The scale structures of the NDI, the Quick DASH, and the RMQ questionnaires are very different. To allow scores to be fitted into the same model, the scores were standardized by nearest centile and converted into a 0–100 score, with 100 being the highest level of disability.

All statistical analyses were performed using Stata Version 13 (StataCorp LP, College Station, TX, USA).

Table 2. Estimates of the SWE for physiotherapy (n = 160)

Pain site	SWE pain ^a		SWE disability ^a		SWE recovery ^b	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Total	24.2 (15.8)	20 (10, 30)	25.0 (16.5)	20 (10, 30)	10.3 (6.2)	10 (7, 14)
Lower back	24.2 (15.9)	20 (10, 40)	26.5 (17.8)	20 (10, 40)	10.3 (6.7)	9.5 (7, 14)
Shoulder	26.4 (17.8)	30 (10, 30)	26.3 (17.3)	25 (10, 40)	10.6 (5.9)	10 (7, 14)
Neck	21.2 (12.7)	20 (10, 30)	21.0 (12.6)	20 (10, 30)	9.8 (5.8)	9 (7, 14)

Abbreviation: SD, standard deviation; IQR, interquartile range; SWE, smallest worthwhile effect.

^a % improvement.

^b Days.

Table 3. Results of regression analyses of the SWE for physiotherapy

Variables	SWE Paint		SWE Disability ^a
	Crude	Adjusted ^c	Crude
Pain site			
Low back	ref.	ref.	ref.
Shoulder	2.37 (−4.33, 9.08)	3.13 (−3.53, 9.78)	−0.12 (−7.18, 6.95)
Neck	−3.11 (−7.94, 1.72)	−0.35 (−7.09, 6.38)	−5.74 ^e (−11.28, −0.19)
Gender			
Women	ref.	ref.	ref.
Men	1.99 (−2.23, 6.22)	1.12 (−3.62, 5.85)	3.73 (−0.29, 7.76)
Age ^d	0.06 (−0.11, 0.22)	0.24 (−0.07, 0.55)	0.02 (−0.11, 0.15)
Work status			
Working	ref.	ref.	ref.
Sick leave/subsidized job	−6.22 (−15.82, 3.37)	−5.23 (−13.99, 3.52)	−5.21 (−12.79, 2.35)
Unemployed/leave/training	5.10 (−7.07, 17.27)	9.30 (−3.76, 22.38)	9.75 ^e (0.28, 19.23)
Retired	0.63 (−4.26, 5.52)	−2.98 (−13.49, 7.53)	−0.20 (−4.80, 4.40)
Previous physiotherapy			
No	ref.	ref.	ref.
Yes	−0.91 (−7.71, 5.90)	−1.34 (−8.45, 5.77)	−1.16 (−7.56, 5.24)
Private health insurance			
No	ref.	ref.	ref.
Yes	−0.25 (−6.20, 5.70)	−0.91 (−8.48, 6.66)	0.87 (−5.82, 7.57)
Duration of symptoms			
<3 months	ref.	ref.	ref.
>3 months	−1.85 (−8.21, 4.51)	−4.87 (−11.16, 1.42)	−3.07 (−9.72, 3.57)
Taking pain medication (daily)			
No	ref.	ref.	ref.
Yes	−4.86 ^e (−8.60, −1.13)	−6.20 (−10.05 ^e , −2.36)	−4.69 ^e (−7.74, −1.64)
Intake scores			
Pain, 0–10 ^d	0.05 (−1.12, 1.22)	0.43 (−1.03, 1.89)	0.14 (−1.15, 1.44)
Disability level, 0–100 ^d	−0.04 (−0.15, 0.06)	−0.08 (−0.26, 0.10)	−0.05 (−0.15, 0.04)
Fear avoidance, 0–20 ^d	0.16 (−0.45, 0.77)	0.39 (−0.32, 1.10)	0.23 (−0.33, 0.79)
Psychological well-being, 0–100 ^d	−0.02 (−0.14, 0.10)	−0.09 (−0.26, 0.07)	0.02 (−0.13, 0.09)

^a Mean differences of % improvement (95% confidence interval) analyzed interval linear regression.

^b Values are mean differences in days (95 % confidence interval) analyzed by linear regression.

^c Adjusted for all other variables shown.

^d Difference per 1 unit increase in values.

^e *P*-value <0.05.

The study was approved by the Danish Data Protection Agency (No. 2012-58-006). As treatment was not affected by participation in the study, under Danish law, this study needed no ethics approval (*Act on Research Ethics Review of Health Research Projects, October 2013*) [36]. The study was funded by the Research Foundation of General Practice, the Central Denmark Region and The Danish Rheumatism Association.

3. Results

The flow of the participants in the study is presented in Fig. 1. A total of 272 patients were contacted by phone, 23

(8%) of whom declined to participate in the interview. An additional 52 patients (20%) were not eligible according to the inclusion criteria. Another 37 (14%) were excluded due to treatment cancellation or delay, withdrawal, and missing intake data, leaving 160 patients for the present study. The characteristics of the included patients are presented in Table 1. The distributions of patients with respect to pain location were as follows: low-back pain 41%, shoulder pain 33%, and neck pain 26%.

3.1. SWE of physiotherapy

Table 2 presents the SWE estimates for the three outcomes; pain, disability, and days to recovery. The median

SWE Disability ^a	SWE Recovery ^b	
	Crude	Adjusted ^c
ref.	ref.	ref.
0.52 (−6.03, 7.07)	0.33 (−2.42, 3.08)	0.23 (−1.99, 2.44)
−2.62 (−9.36, 4.10)	−0.47 (−2.72, 1.77)	0.21 (−2.17, 2.59)
ref.	ref.	ref.
2.87 (−1.25, 7.00)	0.48 (−1.28, 2.24)	0.16 (−1.90, 2.21)
0.29 ^e (0.03, 0.56)	−0.13 (−0.10, 0.07)	0.01 (−0.10, 0.12)
ref.	ref.	ref.
−3.59 (−12.16, 4.26)	−0.64 (−4.14, 2.85)	0.43 (−2.78, 3.64)
17.58 ^e (6.52, 28.64)	4.59 ^e (2.13, 7.05)	6.63 ^e (3.84, 9.43)
−5.03 (−16.20, 6.15)	0.52 (−1.86, 2.91)	1.43 (−3.29, 6.15)
ref.	ref.	ref.
−0.73 (−6.70, 5.24)	0.93 (−1.67, 3.54)	1.47 (−0.57, 3.50)
ref.	ref.	ref.
−0.18 (−9.25, 8.90)	0.50 (−1.85, 2.84)	1.12 (−1.50, 3.75)
ref.	ref.	ref.
−5.99 (−12.55, 0.58)	−0.03 (−2.34, 2.27)	−0.63 (−2.88, 1.61)
ref.	ref.	ref.
−6.52 ^e (−10.91, −2.13)	−1.66 (−4.12, 0.80)	−2.17 (−4.79, 0.45)
0.41 (−1.20, 2.01)	−0.05 (−0.55, 0.45)	0.23 (−0.40, 0.86)
−0.08 (−0.26, 0.09)	−0.03 (−0.66, 0.01)	−0.04 (−0.10, 0.01)
0.45 (−0.22, 1.12)	0.62 (−0.19, 0.31)	0.20 (−0.04, 0.44)
−0.06 (−0.20, 0.08)	0.01 (−0.05, 0.08)	0.01 (−0.08, 0.09)

SWE for additional improvement on pain and disability was 20% (interquartile range [IQR] 10%–30%), and the median SWE for time to recovery was 10 days (IQR 7–14 days) over a period of 6 weeks. Generally, the perceived worthwhile effects for the three outcomes were slightly smaller among patients with neck pain than among patients with low back and shoulder pain.

3.2. Influence of sociodemographic, clinical, and psychological factors

The results of the simple (crude) and multivariable regression linear analyses are presented in Table 3. In the crude

analysis, pain location was not significantly associated with the SWE for pain and days to recovery, but the SWE estimates for disability were found to be significantly lower among patients with neck pain (mean difference −5.74; 95% CI: −11.28, −0.19). These differences, however, did not persist when adjusting for sociodemographic, clinical, and psychological factors in the multivariable analysis. Taking pain medication was significantly associated with lower estimates of pain (mean difference −6.20; 95% CI: −10.05, −2.36) and disability (mean difference −6.52; 95% CI: −10.91, −2.13), whereas this association was weaker and did not reach statistical significance for days to recovery (Table 3). Two additional variables, age and work status, were significantly

associated with the SWE of physiotherapy. Being unemployed, on leave from work, or in training were associated with higher SWE estimates for disability (mean difference 17.58; 95% CI: 6.52, 28.64) and days to recovery (mean difference 6.63; 95% CI: 3.84, 9.43), whereas weaker and nonsignificant associations were found for pain. Older age was associated with higher SWE estimates, but only for disability (mean difference: 0.29; 95% CI: 0.03, 0.56).

4. Discussion

In this study, SWE estimates for physiotherapy among neck, shoulder, and low-back patients were determined and compared. Patients need to experience at least a 20% additional improvement on pain and disability and to speed up their recovery by 10 days to consider that the effect of physiotherapy is worthwhile given its costs, potential side effects, and inconveniences. These effect estimates did not significantly differ by primary pain complaint (neck, shoulder, or back) but were—to a limited extent—influenced by age, regular usage of pain medication, and work status.

Our study included a consecutive sample of patients recruited from many physiotherapy practices and therefore likely to be representative of the typical patient seeking physiotherapy treatment for neck, shoulder, and back pain. A limitation of this study is that 22% of the invited patients declined the offer or had to be excluded due to missing intake data, a fact which could affect the generalizability of our findings. However, these numbers most likely reflect general difficulties with recruitment and data collection in routine clinical practice rather than systematic selection. Furthermore, our sample size did not completely fulfill the minimum requirement for the neck pain group, which may have affected the precision of these estimates. The current design did not allow us to assess the reliability of SWE estimates elicited by the structured interview, which is a limitation of our study. On the other hand, SWE estimates have previously been shown to remain stable over time when conducted by a trained interviewer [15]. Although, data on SWE were collected in a highly standardized manner, they were based on the patients' perspective only. Clinicians' and policy makers' views on how large the effect of an intervention should be to justify its cost, potential risk, and inconveniences may differ from patients' views. Nevertheless, as the effect of interventions for musculoskeletal disorders is evaluated mainly by patient-reported outcome measures, we chose to focus on the patient perspective. In contrast to anchor- and distribution-based methods, the benefit-harm trade-off approach is based on differences in outcome with or without an intervention. This is achieved by asking the patients to consider how much improvement in symptom severity, in addition to the improvement that would likely occur without intervention, would make the intervention worthwhile. However, a possible drawback of this method would be if the magnitude of natural improvement

independently influences the patients' perception of SWE—for example, a lower threshold for improvement with no treatment (natural course) could increase SWE estimates and visa versa. This may be examined by ascribing and comparing various thresholds for natural improvement when collecting data on SWE in the future. Another limitation is that the benefit-harm trade-off methodology only allows the hypothetical effect of the intervention to vary, whereas other attributes such as cost and time spend on treatment are held constant. A recent study suggested a possible influence on SWE estimates of such attributes among older people, when offered an exercise program to prevent falls [37]. Whether similar may apply for our physiotherapy sample is unknown and needs further investigation.

To our knowledge, this is the first study using the benefit-harm trade-off method to compare SWE estimates for the three largest patient groups treated in primary physiotherapy care practice. Our results suggest that patients need to see a reduction in pain and disability equivalent to 20 points on a 100-point scale to perceive that the effect of physiotherapy is worthwhile. Results from Cochrane reviews show that in people with neck, shoulder, and low-back pain, when compared with no treatment, the effect of manual therapy and exercise on pain and disability averages about 10 points on a 100-point scale [38–42]. According to our study, only 25% of the patients seeking physiotherapy for neck, shoulder, or back pain would consider these effects large enough to compensate for the costs, potential side effects, and inconveniences of physiotherapy.

The results of the present study resemble previous findings observed by Ferreira et al. for chronic back pain patients [15], although we observed slightly higher SWE estimates for disability. Similar to their results, we found that these estimates were not influenced by the severity of symptoms, mood, or by symptom intensity. The finding that SWE estimates were unaffected by pain location, past experience with physiotherapy and private health insurance adds on to these previous results. The latter findings should be interpreted in the context of health care systems, as the direct out-of-pocket expenses in relation to physiotherapy in Denmark are relatively modest (an average cost of 25 US dollars per session). Furthermore, the physiotherapy treatment “package” may vary across countries.

Although multivariable analysis revealed that age, usage of pain medication, and work status were significantly associated with SWE estimates, these associations were not consistent across the three outcomes: pain, disability, and time to recovery. The findings with respect to work status should be interpreted with caution as numbers were limited for some categories. Even after adjusting for pain intensity and duration, the thresholds for SWE estimates remained lower among patients taking pain medication on a daily basis than among those who were not. However, as these differences were small, the clinical importance of these findings could be questioned. This may also apply to the improvement in disability for patients of older age.

In sum, the SWE of an intervention is defined as the smallest beneficial effect that is large enough to justify the use of the intervention in clinical practice, taking into account the cost, risk, and inconveniences of the intervention. Over a period of 6 weeks, physiotherapy interventions need to offer at least an additional 20% improvement and speed up recovery by 10 days to be considered worthwhile by people seeking treatment for neck, shoulder, or back pain in primary care. Findings from the present study may guide clinicians and policy makers when interpreting findings from clinical trials and setting standards when monitoring clinical guidelines in the Danish primary care setting. Moreover, they may allow researchers to design trials that are sufficiently powered to detect effects that a typical care-seeking patient would consider large enough to be worthwhile.

Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jclinepi.2018.05.019>.

References

- [1] Briggs AM, Cross MJ, Hoy DG, Sanchez-Riera L, Blyth FM, Woolf AD, et al. Musculoskeletal health conditions represent a global threat to healthy aging: a report for the 2015 World health organization World report on ageing and health. *Gerontologist* 2016;56(Suppl 2):S243–55.
- [2] Moth G, Olesen F, Vedsted P. Reasons for encounter and disease patterns in Danish primary care: changes over 16 years. *Scand J Prim Health Care* 2012;30:70–5.
- [3] de Vos Andersen NB, Kent P, Hjort J, Christiansen DH. Clinical course and prognosis of musculoskeletal pain in patients referred for physiotherapy: does pain site matter? *BMC Musculoskelet Disord* 2017;18:130.
- [4] Babatunde OO, Jordan JL, Van der Windt DA, Hill JC, Foster NE, Protheroe J. Effective treatment options for musculoskeletal pain in primary care: a systematic overview of current evidence. *PLoS One* 2017;12:e0178621.
- [5] Jaeschke R, Singer J, Guyatt GH. Measurement of health status. Ascertaining the minimal clinically important difference. *Control Clin Trials* 1989;10:407–15.
- [6] Ferreira ML, Herbert RD, Ferreira PH, Latimer J, Ostelo RW, Nascimento DP, et al. A critical review of methods used to determine the smallest worthwhile effect of interventions for low back pain. *J Clin Epidemiol* 2012;65:253–61.
- [7] MacDermid JC, Walton DM, Avery S, Blanchard A, Etruw E, McAlpine C, et al. Measurement properties of the neck disability index: a systematic review. *J Orthop Sports Phys Ther* 2009;39:400–17.
- [8] Revicki D, Hays RD, Cella D, Sloan J. Recommended methods for determining responsiveness and minimally important differences for patient-reported outcomes. *J Clin Epidemiol* 2008;61:102–9.
- [9] de Vet HC, Terwee CB, Ostelo RW, Beckerman H, Knol DL, Bouter LM. Minimal changes in health status questionnaires: distinction between minimally detectable change and minimally important change. *Health Qual Life Outcomes* 2006;4:54.
- [10] Barrett B, Harahan B, Brown D, Zhang Z, Brown R. Sufficiently important difference for common cold: severity reduction. *Ann Fam Med* 2007;5:216–23.
- [11] McNamara RJ, Elkins MR, Ferreira ML, Spencer LM, Herbert RD. Smallest worthwhile effect of land-based and water-based pulmonary rehabilitation for COPD. *ERJ Open Res* 2015;1:00007–2015.
- [12] Duric VM, Fallowfield LJ, Saunders C, Houghton J, Coates AS, Stockler MR. Patients' preferences for adjuvant endocrine therapy in early breast cancer: what makes it worthwhile? *Br J Cancer* 2005;93:1319–23.
- [13] Duric VM, Stockler MR, Heritier S, Boyle F, Beith J, Sullivan A, et al. Patients' preferences for adjuvant chemotherapy in early breast cancer: what makes AC and CMF worthwhile now? *Ann Oncol* 2005;16:1786–94.
- [14] Duric VM, Butow PN, Sharpe L, Heritier S, Boyle F, Beith J, et al. Comparing patients' and their partners' preferences for adjuvant chemotherapy in early breast cancer. *Patient Educ Couns* 2008;72:239–45.
- [15] Ferreira ML, Herbert RD, Ferreira PH, Latimer J, Ostelo RW, Grothe M, et al. The smallest worthwhile effect of nonsteroidal anti-inflammatory drugs and physiotherapy for chronic low back pain: a benefit–harm trade-off study. *J Clin Epidemiol* 2013;66:1397–404.
- [16] Terwee CB, Roorda LD, Dekker J, Bierma-Zeinstra SM, Peat G, Jordan KP, et al. Mind the MIC: large variation among populations and methods. *J Clin Epidemiol* 2010;63:524–34.
- [17] Bilde L, Ankjaer-Jensen A, Danneskiold-Samsøe B. The “Health Benefit Basket” in Denmark: a description of entitlements, actors, and decision-making processes in the curative health sector. *Eur J Health Econ* 2005;6(Suppl):11–7.
- [18] Budtz CR, Andersen NB, Qvist I, Pedersen F, Ladegourdier V, Ottosen J, et al. Monitoreringsprojekt fysioterapipraksis 2016: Kan en IT-baseret grundmodel for udredning, behandling og kommunikation implementeres i praksissektoren? [Project on monitoring physiotherapy practice: can standardised electronic data collection tools be implemented?]. Available at: <https://www.sundhed.dk/sundhedsfaglig/information-til-praksis/midtjylland/fysioterapeut/rapporter-mm/monitoreringsprojekt/>. Accessed May 2018.
- [19] Vasseljen O, Woodhouse A, Bjørngaard JH, Leivseth L. Natural course of acute neck and low back pain in the general population: the HUNT study. *Pain* 2013;154:1237–44.
- [20] Artus M, van der Windt D, Jordan KP, Croft PR. The clinical course of low back pain: a meta-analysis comparing outcomes in randomised clinical trials (RCTs) and observational studies. *BMC Musculoskelet Disord* 2014;15:68.
- [21] Muller U, Tenzler K, Burger A, Staub L, Tamcan O, Roeder C, et al. A pain assessment scale for population-based studies: development and validation of the pain module of the standard evaluation questionnaire. *Pain* 2008;136:62–74.
- [22] Mannion AF, Balague F, Pellise F, Cedraschi C. Pain measurement in patients with low back pain. *Nat Clin Pract Rheumatol* 2007;3:610–8.
- [23] Lauridsen HH, O'Neill L, Kongsted A, Hartvigsen J. The Danish neck disability index: new insights into factor structure, generalizability, and responsiveness. *Pain Pract* 2017;17(4):480–93.
- [24] Lundquist CB, Dossing K, Christiansen DH. Responsiveness of a Danish version of the disabilities of the arm, shoulder and hand (DASH) questionnaire. *Dan Med J* 2014;61:A4813.
- [25] Franchignoni F, Vercelli S, Giordano A, Sartorio F, Bravini E, Ferriero G. Minimal clinically important difference of the disabilities of the arm, shoulder and hand outcome measure (DASH) and its shortened version (QuickDASH). *J Orthop Sports Phys Ther* 2014;44:30–9.
- [26] Albert HB, Jensen AM, Dahl D, Rasmussen MN. [Criteria validation of the Roland Morris questionnaire. A Danish translation of the international scale for the assessment of functional level in patients with low back pain and sciatica]. *Ugeskr Laeger* 2003;165:1875–80.
- [27] Roland M, Fairbank J. The Roland-Morris disability questionnaire and the Oswestry disability questionnaire. *Spine* 2000;25:3115–24.
- [28] Westman A, Linton SJ, Ohrvik J, Wahlen P, Leppert J. Do psychosocial factors predict disability and health at a 3-year follow-up for patients with non-acute musculoskeletal pain? A validation of the Orebro musculoskeletal pain screening questionnaire. *Eur J Pain* 2008;12:641–9.
- [29] Hockings RL, McAuley JH, Maher CG. A systematic review of the predictive ability of the Orebro musculoskeletal pain questionnaire. *Spine* 2008;33:E494–500.

- [30] Linton SJ, Hallden K. Can we screen for problematic back pain? A screening questionnaire for predicting outcome in acute and subacute back pain. *Clin J Pain* 1998;14:209–15.
- [31] Topp CW, Ostergaard SD, Sondergaard S, Bech P. The WHO-5 well-being index: a systematic review of the literature. *Psychother Psychosom* 2015;84:167–76.
- [32] Folker H, Folker AP. WHO-5 as a simple method for measuring quality of life in daily psychiatric clinics. *Ugeskr Laeger* 2008;170: 830–4.
- [33] Terwee CB, Bot SD, de Boer MR, van der Windt AWM, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol* 2007;60: 34–42.
- [34] Austin PC, Steyerberg EW. The number of subjects per variable required in linear regression analyses. *J Clin Epidemiol* 2015;68:627–36.
- [35] Cameron AC, Trivedi PK. *Microeconometrics Using Stata*. Rev. College Station, TX: Stata Press; 2010.
- [36] Danish National committee on biomedical research ethics. Act on research ethics review of health research projects. 2013. Available at: <http://www.nvk.dk/english/act-on-research>. Accessed May 2018.
- [37] Franco MR, Howard K, Sherrington C, Rose J, Ferreira PH, Ferreira ML. Smallest worthwhile effect of exercise programs to prevent falls among older people: estimates from benefit-harm trade-off and discrete choice methods. *Age Ageing* 2016;45:806–12.
- [38] Page MJ, Green S, McBain B, Surace SJ, Deitch J, Lyttle N, et al. Manual therapy and exercise for rotator cuff disease. *Cochrane Database Syst Rev* 2016;CD012224.
- [39] Gross AR, Paquin JP, Dupont G, Blanchette S, Lalonde P, Cristie T, et al. Exercises for mechanical neck disorders: a Cochrane review update. *Man Ther* 2016;24:25–45.
- [40] Gross A, Langevin P, Burnie SJ, Bedard-Brochu MS, Empey B, Dugas E, et al. Manipulation and mobilisation for neck pain contrasted against an inactive control or another active treatment. *Cochrane Database Syst Rev* 2015;CD004249.
- [41] Rubinstein SM, Terwee CB, Assendelft WJ, de Boer MR, van Tulder MW. Spinal manipulative therapy for acute low-back pain. *Cochrane Database Syst Rev* 2012;CD008880.
- [42] Rubinstein SM, van Middelkoop M, Assendelft WJ, de Boer MR, van Tulder MW. Spinal manipulative therapy for chronic low-back pain. *Cochrane Database Syst Rev* 2011;CD008112.